Nerve And/Or Muscle Stimulation Electrodes

The present invention relates to the biomedical arts, particularly neuromuscular electrical stimulation (NMES) by means of surface electrodes and includes apparatus for interfacing an electronic stimulator and a surface electrode with multiple contacts. The invention facilitates the selection of the most appropriate positions of electrodes used for stimulation of sensory-motor systems in humans.

Electrical stimulation of nerves and muscles by means of surface electrodes is now being used for various applications, including pain reduction, muscle strengthening, activation of paralysed muscles, spinal cord stimulation and training of sensory-motor mechanisms. Common to all uses of surface electrodes for stimulation is that it requires a great deal of skill and patience of the user and/or the therapist to place the electrodes in the optimal position for the function to be performed. It is impossible to know precisely the pathways of the electrical charge that should be delivered to sensory-motor systems under the skin. It is therefore difficult to predict precisely which anatomic structures will be activated for any given position and electrode configuration. Very often self-adhering electrodes are used, which must be taken off completely before they can be repositioned at a different location on the skin. This process is not only frustrating and time-consuming, but can also be painful and compromises the adhesion of the electrode to the skin, leading to an increased consumption of electrodes. Further, it is difficult to try many different electrode sizes, even if this may have an important effect on the function and subjective perception of the stimulation. For these reasons a non-optimal electrode position and electrode size are often chosen.

The present invention addresses this problem of the
effective use of surface electrodes. It is proposed to use a
multiple contact surface stimulation electrode combined with
an easy-to-use interface, which allows the user to rapidly
5   emulate many different electrode sizes and positions, without
actually removing the electrode from the skin during the
process.

US6564079 discloses an electrode array comprising a
common adhesive substrate carrying a number of spaced
10   electrodes for use in mapping nerve locations. The electrode
array is to be connected to a peripheral nerve detection
instrument, the nature of which is not described. Contacts
lead from each electrode to electronic circuitry comprising
multiplexers and a shift register, but again the exact
15   purpose of this circuitry is not described. It is not
disclosed that nerves or muscles should be stimulated or that
any voltage is to be applied to the electrodes.

The present invention now provides a nerve or muscle
stimulation apparatus comprising:
20   a nerve stimulation array electrode comprising a substrate
for application to the skin of a user bearing an array of
electrodes arranged to be brought into electrical contact
with the skin of a user when the substrate is positioned on
said skin,

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one or more input contacts, the or each said input contact
being switchably electrically connected to a group of
electrodes consisting of some or all of said electrodes, and

30   user operable switch means for performing said electrical
connection by making and breaking electrical connection
between the or each said input contact and any selected one
or ones of its respective group of said electrodes.

Thus, the array of electrodes provided by the invention allows the array to be positioned generally in an area in which precise stimulation of underlying nerves or muscles is required and for the array to be configured in situ by the

5   selection of an appropriate electrode, or appropriate electrodes as a group or a number of groups, which are ideally placed to achieve the desired effects. There is therefore no need to establish the precise position at which electrical stimulation is required before the electrode is

10   placed or to remove and replace the electrode to achieve the desired position. Instead, the array may be placed in approximately the required position and then configured as described above. One therefore avoids the need for extensive trial and error positioning of electrodes. One is therefore

15   able to select one or more ideally placed contacts as an interface for the delivery of controlled amounts of electrical charge to sensory-motor systems.

The electrodes may be arranged on the substrate in a random manner or in any desired pattern, but it will

20   generally be convenient if said substrate bears an array of electrodes arranged in rows and/or columns. This includes arrangements in which not every point in a row and column array is filled, e.g. hexagonal arrays.

Preferably, there are at least 12 electrodes in the

25   array, more suitably at least 18 or at least 24 electrodes in the array. However, there may be fewer electrodes than this, e.g. 6 or more. The fewer electrodes there are, the more accurate will need to be the placement of the array.

Normally it will be preferable that the electrodes are

30   evenly spread over the substrate. This will maximise the chance that one or several of the electrodes are in the ideal position.

Preferably, the maximum space between adjacent electrodes is no more than 5 cm. More preferably, it is less, e.g. no more than 2 cm. However, the spacing is preferably substantially less, e.g. no more than 1 cm. Still

5   more preferably, the spacing does not exceed 3mm. Suitably, the spacing is about 1mm or does not exceed 1mm.

Preferably, each electrode is not more that 5 cm in maximum dimension, more preferably no more than 2 cm, e.g. about 1 cm.

10   The size and spacing of the electrodes is suitably chosen to ensure that the charge delivered and the current density will be within safety margins and standards taking into account the stimulation pattern. Relevant parameters to take into account will include the pulse duration and pulse

15   amplitude.

The switch means may be carried by the substrate. Alternatively, the switch means may be carried by a separate controller. Suitably, the switch means comprises a respective manually operable switch associated with each

20   electrode.

Optionally, the switch means comprises:
an electronic user interface unit adapted to receive a user input representing an electrode selection and to communicate data signals representing said selection to an electronic

25   switching unit; and
a said electronic switching unit adapted to receive said data signals and to perform connection of selected electrodes to said input contact(s).

Said electronic user interface unit may be adapted to

30   accept programming to alter said selection of electrodes to accommodate said selection to alterations in the desired site of stimulation with time or user muscle movement. The desired surface position of stimulation may alter as the

patient's limb moves or as the relevant muscles move under
the skin surface upon stimulation. It should be appreciated
also that one of the problems experienced in this field is
that repeated use of nerve or muscle stimulation apparatus is
5   that by exercising muscles or muscle groups the geometry of
the relevant body part is changed, so that previously ideal
electrode sites become less than ideal. The array electrode
of the invention allows for these changes to be accommodated
either by responding to the changes with reconfiguration of
10   the electrode array in a trial and error manner from time to
time or by a pre-programmed reconfiguration.

Optionally, said electronic switching unit is mounted to
said substrate and said electronic user interface unit is
remote from said substrate and is wirelessly connected or in
15   wired connection with said electronic switching unit.

In addition to said array electrode, the apparatus may
comprise one or more further electrodes connected to said
switch means. In particular, there may be a common ground or
counter electrode, which will not generally need also to be
20   in the form of an array, but may be if desired.

Preferably, the user operable switch means is operable
to make connection between the or a said input contact and a
first electrode set constituted by a selected one or selected
ones of its respective group of electrodes and with a second
25   electrode set constituted by a selected one or selected ones
of its respective group of electrodes, leaving disconnected
at least one further electrode positioned between said first
and second electrode sets. For instance, it has been noticed
that the pattern chosen for stimulation of finger extensors
30   is not a simple geometric shape. It may consist of two
separate groups of active electrodes, such that one activates
two separate muscles that both stretch the fingers whilst not
activating the muscle in between, which extends the wrist.

For situations like this, control arrangements that allow
discontinuously arranged electrodes to be grouped for
simultaneous activation, such as individual on/off switches
for each electrode, may be preferred over arrangements that
5   only allow adjacent electrodes to be grouped.

The apparatus may further comprise a source of nerve or
muscle stimulation signals connected to the or a said input
contact.

The invention will be further described and illustrated
10   with reference being made to the accompanying drawings in
which:-

Figure 1 is an organisational schematic of apparatus for
use in the invention;

Figure 2 is a schematic electrical circuit of an array
15   electrode incorporating switches for use in a first
embodiment of the invention;

Figure 3 illustrates a second embodiment of the
invention and shows an array electrode in plan view and a
control unit also in plan view;

20   Figure 4 illustrates a third embodiment of the
invention, showing the operational interaction between its
components, including a plan view of its array electrode; and

Figure 5 shows a fourth embodiment according to the
invention and shows an array electrode in plan view and a
25   control unit also in plan view.

The apparatus of Figure 1 consists of a controller 1
comprising an interface for the operator to control the
apparatus, a switching means 2 which directs the output from
a source of electrical stimulation signals or stimulator 3 to
30   a surface array electrode 4 having multiple electrodes 5
forming an array and in galvanic contact with the skin. The
array electrode is shown as rectangular, but may have any
shape, e.g. be shaped to fit a specific body-part. The

stimulator 3 can be any commercial or custom-made stimulator
suitable for the particular application. The switch means 2
directs the output from the stimulator 3 to one or more of
the multiple electrodes of the array electrode as determined
5   by the controller 1. The controller allows sizing, shaping
and locating of the active area 6 by the operator before or
even during the operation.

The controller 1 allows selection of the most
appropriate contact points for conducting the electrical
10   signals from the stimulator 3 to the tissue. As illustrated
below the interface represented by the controller 1 may be
mechanical or electronic. Where it is electronic, it may
comprise firmware and software to allow wireless
communication of the controller 1 and a PC, Lap-top, or
15   handheld computer for computerized setup.

Four embodiments of the invention are illustrated in
Figures 2 to 5. One is an integrated user interface,
controller and electrode shown in Figure 2; in another the
controller and user interface are separate from the electrode
20   (Figure 3); in that of Figure 4, the controller and user
interface is provided by means of a personal computer; and in
the last, each electrode is controlled by a respective switch
located on a remotely connected control box (Figure 5).

A first embodiment is illustrated in Figure 2. It
25   consists of an array electrode having a substrate pad bearing
many electrodes 103. The substrate is adhesive on one face
(front) on which are positioned the electrodes 103 and has
miniature tactile switches 102 for manual operation embedded
on the back of the array electrode, opposite the stimulating
30   surface. Each switch connects or disconnects the
corresponding electrode 103 in the array on the other side
to/from a common electrical contact input 101. The switches
102 are designed so that the on/off state of each switch can

be clearly seen by the user. In use the electrode is placed roughly over the right location on the skin, whereafter fine-tuning of the placement is done by activating the switches. The electrode is connected via contact 101 to a single

5   channel of an electronic stimulator as would be any other stimulation electrode. The second electrode (counter electrode) in the circuit could be a single contact anode, or a similar array electrode.

     After the electrode is adhered to the skin, by applying

10   electrical stimulation to contact 101 and closing and opening switches 102, a practitioner or patient can find which electrodes in the array contribute most effectively to producing the desired stimulation effect, for instance to produce contraction of a muscle. These may lie adjacent one

15   another or not. A selected set of electrodes may be of any shape and may include from one up to any number of the available electrodes and may form one or several contiguous groupings.

     Although the illustrated array electrode has only one

20   input connection 101 which is connectable in common with each of the electrodes 103 of the array, more than one such contact may be provided and then each may be connectable only to a particular respective group of the available electrodes 103. Such groups will usually be exclusive of one another

25   (so that no electrode 103 is a member of more than one group) but if more complex switching and circuitry is employed may be overlapping (so that some but not all of the electrodes 103 fall into more than one group). Where groups overlap, preferably not all of the electrodes each fall into the same

30   two groups.

     In this and other embodiments, the electrode may be secured in place other than by adhesive, e.g. by a strap.

A second embodiment is illustrated in Figure 3. A
controller 201 is connected to a head-stage 202, by means of
a thin and flexible cable 206. The head-stage includes a
zero-insertion force multi-connector 203 which connects to an
5   array electrode 204. The head-stage also includes an
electronic switching circuit, and the number of conductors in
the cable 206 can be kept at a minimum (3-4 leads) sufficient
to communicate neuromuscular stimulating signals and data
defining electrodes of the array to receive such signals.
10   Each of the electrodes 205 is represented by a light emitting
diode 207, or other indicator, on the controller 201. An
active indicator light shows that the corresponding electrode
contact is connected to the stimulator. An analog or digital
joy-stick 212 controls the location, size and shape of the
15   emulated electrode, indicated by the dashed lines 208. Whilst
a user is pressing the "Size" button 211, the joystick
controls the size and shape of the active area by moving one
corner of the area while keeping the diagonal corner fixed
e.g. in the upper right, as indicated in the figure. When the
20   "Size" button 211 is released, the shape and size of the
active area remains fixed and can then be moved around within
the field by moving the joystick. A stimulator (not shown) is
connected to the controller by means of a pair of leads 209
and connectors 210. The controller contains batteries and may
25   be turned on and off by means of a button 213.

The array electrode 204 again has a substrate having one
adhesive face carrying an array of the electrodes 205, which
may be larger or smaller in terms of the number of electrodes
than the array actually shown. Each electrode is provided
30   with an electrical connection to a respective contact 220 of
the zif connector plug portion, suitably by a conductive
metal track formed on the substrate.

The circuitry in the head stage 202 is adapted to
receive stimulation signals such as shaped biphasic pulses
from the stimulator via the controller 201 and data signals
from the controller 201 indicating to which electrodes

5   selected from the whole array the signals should be
connected. Based on these data signals, the circuitry of the
head stage acts as a solid state switch means for each
electrode of the array to connect the stimulation signals to
the selected electrodes in common.

10   As in Figure 2, the electrodes of the array electrode
may form a single group from which a selection is made for
connection to the same stimulation signals or may be divided
into discrete or overlapping groups to receive the same or
different stimulation signals.

15   Instead of the illustrated joystick arrangement, any
alternative manual input method may be used for determining
which electrodes in the array are to be connected. For
instance, hardware switches (as in Figure 2) may be provided
on the controller 201 in an array mirroring the electrode

20   array, as shown in more detail in Figure 5.

The third embodiment includes a computer 301, which can
be a standard PC, laptop or handheld. A touchpad, mouse,
joystick, touch-sensitive screen or other standard pointing
device serves as the input means for selecting the active

25   area of the electrode. Different areas and shapes of the
active area can be selected on the computer screen, which
also shows the active area or areas during stimulation. The
computer controls the switching box, either by a wired or a
wireless connection (such as a standard infrared (IR) link or

30   a radio link such as used by wireless keyboards and mice).
Computer control adds the option of providing rapid changes
in "electrode position", which could be used for e.g.
compensating for movement of the activated muscle. This is an

often encountered problem when using standard surface
electrodes. The motor point for a relaxed muscle may be
different than that for a contracted muscle. The movement of
the motor point can be entered into the computer, which can

5   then compensate for this if it is informed of the timing and
intensity of the stimulation. The latter is done by a trigger
signal 302 being sent from the stimulator to the computer as
shown or by feedback signal being sent from a movement sensor
responding to changes in the muscle. The switch may be

10   incorporated in a head stage connected to the array electrode
as in Figure 3.

     Another embodiment is illustrated in Figure 5. It
consists of an array electrode 256 having a substrate bearing
a plurality of electrodes 257.

15   The substrate is fabricated from a flexible material in
order to be mounted on the selected part of the body. The
substrate connects via a cable 254 to a controller box 251
with a zero insertion force multi-connector 255. The
controller box comprises a plurality of tactile switches 253

20   that are positioned to match geometrically the positions of
the plurality of electrodes. The tactile switches have
respective indicators that by lighting show when each is in
the on state. The controller box connects to the anode and
cathode 252 of the stimulator that delivers monophasic,

25   monophasic compensated, or biphasic bursts of stimulation
pulses. The control box comprises a microcomputer that uses
switches as inputs in order to connect the stimulator output
to the selected electrodes in the array electrode.

     All electrodes (cathodes) 257 stimulate with respect to

30   a common anode 258 connected via a line connector 259, which
anode may be a standard surface electrode or a similar array
electrode.

In a modification of this embodiment is a device
generally as shown in the figure 5 but where each switch in
the array of mechanical switches shows its state by the
position it is in. The controller in such a device does not
5   require any power and can be made very cheaply.

All embodiments have been illustrated as for a single
channel stimulator to be connected to the device. It is
however simple to envision how the devices can be connected
to a multi-channel stimulator. An extra button/dial on the
10   user interface can allow the user to setup different
electrode contact areas for different channels and the
controller must then be able to differentiate between
stimulation pulses entering on different input channels and
direct them to the desired electrode contacts. The channels
15   may be multiplexed, so that no two channels are active to
send out current at precisely the same time.

An example of an application for such a multi-channel
device could be a stimulation system for restoring hand
function. To obtain even a rudimentary grasp function of a
20   paralysed hand, it is necessary to apply four channels of
stimulation (finger extension, finger flexion, thumb
extension and thumb flexion). Some of (potentially all four)
electrodes and the reference electrode in such a system can
be replaced by a single large multi-channel electrode of the
25   type described above.

In this specification, unless expressly otherwise
indicated, the word 'or' is used in the sense of an operator
that returns a true value when either or both of the stated
conditions is met, as opposed to the operator 'exclusive or'
30   which requires that only one of the conditions is met. The
word 'comprising' is used in the sense of 'including' rather
than in to mean 'consisting of'.